

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
_____)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:)	
)	
All Cases.)	
)	<i>Leave to file granted</i>
_____)	<i>Docket No. 1222</i>

**SAINT THOMAS ENTITIES AND ASCENSION PARTIES' CONSOLIDATED BRIEF
AS TO DISCOVERY PLAN AND BELLWETHER ISSUES**

With leave of Court,¹ Defendants Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the “Saint Thomas Entities”) and Defendants Ascension Health and Ascension Health Alliance (collectively referred to as the “Ascension Parties”) file this consolidated brief to address the outstanding discovery plan and bellwether issues that have been referred to this Court for a decision.

PRELIMINARY STATEMENT

The Court has set a hearing on July 17, 2014 on the *Saint Thomas Entities' Motion to Stay Objections and Responses to Discovery Pending Submission of a Discovery Plan and Amended Protective Order* (Docket #595) (“Discovery Motion”) and the *Plaintiffs' Steering Committee's (“PSC's”) Motion for Entry of a Bellwether Trial and Pre-Trial Scheduling Order* (Docket #837) (“Bellwether Motion”). These motions are interrelated and were briefed over the

¹ The Court has previously granted leave to submit this consolidated brief. *See* Docket #1222.

course of several months beginning in fall of 2013.² The issues relating to the discovery plan and bellwether proposals are embedded in multiple documents, significant portions of which have been resolved by other rulings or rendered obsolete due to the passage of time and intervening circumstances. To give but one example, the PSC’s Bellwether Motion—which is one of the motions specifically referred for the July 17 hearing—proposes that the “Plaintiffs in every filed action naming one or more S[aint] Thomas-Related Defendants will serve completed Plaintiff Profile Forms (“PPF”) and medical authorizations within 60 days after the form PPF and medical authorizations are approved by the Court or Magistrate Court.” Docket #837-1 at 2 ¶ C. The Court approved the forms of Fact Sheets and records authorizations on February 14, 2014 (Docket #923), but now—almost five months from that date—the PSC has yet to provide a single completed Fact Sheet or court-ordered records authorization to these Defendants. The other dates in the PSC’s proposed bellwether schedule have likewise either passed or are currently unworkable. The purpose of this consolidated brief is to summarize the outstanding issues and synthesize the arguments, from the standpoint of these entities, for the Court’s resolution.

RELEVANT BACKGROUND FACTS AND PROCEDURE

A. The Court Enters a Series of Case Management Orders

Before the Saint Thomas Entities and Ascension Parties were parties to this MDL, a number of case management orders were entered at the request of the PSC without input from,

² A relatively complete list of these motions and briefs was provided to the Court in these Defendants’ *Motion for Leave to File a Brief as to Bellwether and Discovery Issues* (Docket #1206).

much less any consensus of, the “Unaffiliated Defendants.”³ These initial Case Management Orders (“CMOs”) were entered in the relative infancy of these cases; before most of the Unaffiliated Defendants became parties in the MDL; after New England Compounding Center (“NECC”) declared bankruptcy; after the Affiliated Defendants⁴ had been granted a stay from discovery; and after the Court provided for a stay of discovery as to any Unaffiliated Defendants who entered into the Court-approved mediation program (*See* Docket #394). Consequently, the defendants affected by these orders did not participate in drafting the orders or the negotiation of their contents. *See* FED. R. CIV. P. 16(b)(1) (requiring issuance of a scheduling order either after receipt of *all* parties’ Rule 26 disclosures or after consulting *all* parties’ attorneys and any unrepresented parties at a scheduling conference).

Notably, one order ostensibly allowed discovery to begin against the Unaffiliated Defendants. *See* MDL Order No. 6 at 13-14 (Docket #209). MDL Order No. 7 has been claimed by the PSC to permit one-sided fact discovery as to the Unaffiliated Defendants to “begin forthwith” in the absence of any plan for discovery (Docket #438). At the same time, it set forth an aggressive timetable for choosing bellwether plaintiffs, providing that only those self-selecting claimants who wished to be considered for bellwether trials would prepare and complete “Plaintiff Profile Forms” containing case-specific information. And, as noted, all discovery was stayed against NECC and the Affiliated Defendants. Remarkably, the PSC’s first proposal deferred any discussion of the parameters of a bellwether selection process indefinitely, yet imposed a deadline for final selections only a few months after the submission of the proposal. *See generally* Docket #421.

³ The “Unaffiliated Defendants” are an unaffiliated group of hospitals, clinics, and other healthcare providers, many of whom have not yet made appearances in this Court, although a few have made limited appearances for the purpose of objecting to third-party subpoenas.

⁴ The term “Affiliated Defendants” is defined in MDL Order No. 7 ¶ 1 (Docket #438).

B. MDL Order No. 7 Is Essentially Retracted

Soon after they were made parties in the MDL, the Saint Thomas Entities filed a *Motion to Reconsider MDL Order No. 7* (Docket #457). They pointed out that the PSC's proposal was entirely unworkable, both in terms of timing and logistics, and could not be adequately or justly implemented in the absence of a bilateral, comprehensive plan for discovery from all parties so that critical information could be obtained to make meaningful selections for bellwether trials.

The PSC's response was to immediately serve the Saint Thomas Entities with "master discovery." Although these Defendants answered the written discovery requests and provided documents that had been previously produced in state court, they also filed motions for stay of discovery pending implementation of a discovery plan and provided the Court with additional briefing as to why such a discovery plan was necessary to streamline the litigation and ensure that the defendants had equal access to the documents, materials, and other information necessary to discover and develop their claims and/or defenses. *See generally* Discovery Motion (Docket #595). They pointed out that the PSC already had access to the individual records of the plaintiffs, as well as a repository of documents obtained from NECC during confidential settlement discussions, while the defendants did not even have authorizations for the release of medical and other records for the plaintiffs.⁵

Over the next few months, Judge Saylor set aside portions of MDL Order No. 7, specifically finding the bellwether proposal to be "premature," and directing the parties to meet and confer about a "discovery plan." See Excerpts from transcript from Jan. 10, 2014 hearing ("Tr.") at 39-41, 47-50 (Exhibit A); *see also* Order on Timetable for Determining Bellwether Cases (Docket #721). The Saint Thomas Entities understood the Court's direction to be to

⁵ Very limited releases were attached to the individual complaints as required by Tennessee law.

attempt to agree on a “plan for discovery,” in accordance with Federal Rules of Civil Procedure 16 and 26(f) and Local Rule 16.1, that:

- “schedul[es] the time and length for all discovery events”; and
- “conform[s] to the obligation to limit discovery set forth in FED. R. CIV. P. 26(b)”.

LR. 16.1(d)(1). The Court indicated that the discovery plan should include an overview of the discovery elements in the case, such as sequencing written discovery and depositions, and an “order that directs and sets deadlines and so on” Tr., Ex. A at 48-50.

Although the parties had several conferences pursuant to the Court’s instructions, they were ultimately unsuccessful, as the PSC took the position that discovery was already authorized and no further “plan” was necessary (based on MDL Order No. 7), and instead offered its second bellwether proposal. *See generally* Declaration of Yvonne K. Puig of Jan. 31, 2014 (Docket #840-2); *see also [Proposed] MDL Order No. ____ Regarding Initial Trial Setting and Pretrial Deadlines for the Saint Thomas-Related Defendants* (Docket #837-1) (“PSC’s Bellwether Proposal”). Without compromising their position that a comprehensive discovery plan was critical, the Saint Thomas Entities and Ascension Parties and a few other defendants agreed to work on particular protocols and forms with the PSC that these defendants intended to be part of a larger discovery plan, and they were able to negotiate a protocol for Electronically Stored Information. But the parties were unable to agree on a form of Plaintiffs’ Fact Sheets, authorizations for the release of individual Plaintiffs’ records, or a deposition protocol. These matters of disagreement were submitted to this Court for resolution.

This Court presided over the dispute over the form of Plaintiffs’ Fact Sheets and records authorizations and issued an order on February 14, 2014 (Docket #923). As noted above, the

PSC has yet to provide a *single* completed Fact Sheet or full records authorization to these Defendants, or to their knowledge, any other defendant.

Nonetheless, the PSC continues to press forward with its proposal for a trial in May 2015, and sets its proposed pretrial deadlines backwards from there. *See, e.g., Plaintiffs' Steering Committee's Reply in Support of Bellwether Trial Plan and Pretrial Scheduling Order* (Docket #1001) at 5 ("The PSC's bellwether trial plan and pretrial scheduling order sets forth a schedule for moving the cases toward trial in May 2015. To reach this goal, discovery as to common issues must continue."). As demonstrated below, the PSC's Bellwether Proposal was submitted in January of this year, several of the proposed deadlines have already passed, and the remainder are either impossible or highly unrealistic. Moreover, the entire proposal suffers from a number of architectural flaws, including the lack of any discovery plan to govern that all-encompassing aspect of the case development. The forms and protocols that have been court-ordered or agreed to thus far do not suffice to substitute for the comprehensive plan envisioned and mandated by FED. R. CIV. P. 26 and Local Rule 16. And as past experience in this case has taught, the lack of a discovery plan will create myriad problems and inefficiencies—not to mention potential injustices. It will no doubt require this Court's repeated intervention to settle ground rules that could and should be resolved in advance of embarking on such a wide-scale discovery process.

ARGUMENT AND AUTHORITIES

I. A Discovery Plan Is Urgently Needed Before Any Further Discovery Is Conducted

A. Complex MDL Proceedings in Particular Require Comprehensive Discovery Protocols

Whether in the form of a Rule 26(f) proposal, or a CMO managing discovery, a protocol is necessary in a case of this magnitude and complexity. Rule 26(f) conferences and comprehensive discovery plans are vital tools for accomplishing efficient case management. *See*

MANUAL FOR COMPLEX LITIGATION (FOURTH) § 11.42 (“A discovery plan should facilitate the orderly and cost-effective acquisition of relevant information and materials and the prompt resolution of discovery disputes. The plan should reflect the circumstances of the litigation, and its development and implementation must be a collaborative effort with counsel.”). Thus, not only do the Rules require that the parties participate in a Rule 26(f) conference before discovery can begin—*see id.* § 11.421 (“Rule 26(f) requires such conferring and places joint responsibility on the attorneys of record and all unrepresented parties to arrange, attend (or be represented at), and participate in good faith in the conference. Rule 26(d) bars discovery, absent stipulation or court order, before that conference.”)—but a discovery plan setting out the rules of engagement would also help the parties structure their relationships going forward and avoid duplicative discovery and wasteful discovery disputes. The parties need ground rules before engaging in written discovery, document production, and depositions. *See* FED. R. CIV. P. 26(f)(3)(B) (plan includes “the subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or limited to or focused on particular issues”); *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 20.132; *In re Foundry Resins Antitrust Litig.*, 342 F. Supp. 2d 1346, 1347 (J.P.M.L. 2004) (prevention of duplicative discovery is one of the purposes of permitting transfer under 28 U.S.C. § 1407).

B. Federal Rule 26 and Local Rule 16 Provide the Framework

Contrary to the PSC’s position on the discovery plan, there has been no finding that Rule 26’s requirements for pre-discovery conferences and a discovery plan have been waived by the Court. Although Judge Saylor previously ordered that discovery may begin, to the undersigned’s knowledge, the Court has said nothing to indicate that a discovery plan was not needed here. To the contrary, the Court expressly directed Plaintiffs’ Lead Counsel to ensure full compliance with Rule 26. *See* MDL Order No. 2 (Docket # 82) at 4 (defining responsibilities, which include “to

coordinate and lead discussions with the Court, plaintiffs’ counsel and other stakeholders . . . to ensure that court orders are followed, schedules are met, discovery is conducted and provided *consistent with the requirements of FED. R. CIV. P. 26, unnecessary expenditures of time and funds are avoided, and any negotiations are reasonably efficient and productive*” (emphasis added)). The PSC has certainly not made any showing of exigent circumstances or other exceptional grounds for bypassing Rule 26’s presumption that a negotiated plan for discovery should be in place before formal discovery begins. This omission is all the more concerning, considering that MDL Order No. 7 was entered without input—much less consensus—from the Saint Thomas Entities (or, for that matter, most of the other defendants).

Rule 26 requires parties to confer and attempt to agree on a proposed discovery plan before a party may seek discovery from “*any source*.” FED. R. CIV. P. 26 (emphasis added). Notwithstanding the clear direction of the rule, these defendants had no opportunity to confer with the PSC about a proposed discovery plan before the discovery was served. Instead, the PSC simply sent out these discovery requests the day after the Court heard argument on the Saint Thomas Entities’ Motion for Reconsideration and directed the parties to attempt to resolve the issues. *See* Docket #519.

Given the complexity of this growing MDL, it is particularly important that the Court enforce Rule 26 and supervise and manage master discovery. A discovery plan could help avoid wasteful discovery disputes and duplicative document productions by allowing the parties to agree on the scope and timing of discovery. Yet, as noted, the PSC served discovery on the Saint Thomas Entities before the parties had conferred under Rule 26(f) to “attempt[] in good faith to agree on [a] proposed discovery plan.” FED. R. CIV. P. 26(f)(2). Thus, the PSC’s discovery is premature because Rule 26(d) prevents a party from “seek[ing] discovery from any source before

the parties have conferred as required by Rule 26(f),” unless the discovery is authorized by the Rules, stipulation, or court order. FED. R. CIV. P. 26(d); *see also Al Odah v. United States*, 329 F. Supp. 2d 106, 108-09 (D.D.C. 2004) (finding plaintiffs’ discovery requests premature because the parties had not yet held a Rule 26(f) discovery conference); *Media Prods., Inc. v. Does 1-49*, No. 12–30084–MAP, 2013 WL 1092128, at *5 (D. Mass. Feb. 15, 2013) (“[Rule 26(d)] provides that: ‘[e]xcept . . . when authorized under these rules or by order or agreement of the parties, a party may not seek discovery from any source before the parties have conferred as required by Rule 26(f).’ (citation omitted)). Similarly, Local Rules 16.1 and 16.3 confirm the need for such a conference and plan, and MDLs are not exempted from this requirement under Local Rule 16.2.

To be clear, the Saint Thomas Entities are not seeking to delay these cases; indeed, they are seeking to streamline the litigation. After their Motion to Reconsider was heard by the Court, they promptly submitted proposed CMOs to the PSC regarding pleadings, bellwether selection, and discovery protocols. *See* Declaration of Marcy Hogan Greer (Docket #593 at ¶ 8. Many of those proposals have previously been heard and decided by the Court. The entry of a CMO containing a discovery protocol will move the cases forward, leaving the parties to address only discrete discovery issues rather than having to tackle a broad discovery plan all at once. The PSC’s refusal to meaningfully engage in discussions about the proposed CMO concerning discovery protocols has limited the parties’ abilities to move forward with the cases in an organized, efficient manner.

The Saint Thomas Entities have proposed reasonable, bilateral procedures along the lines of ones adopted in other MDLs, while the PSC wants to bind them to a process that severely limits the discovery available to the defendants and pushes forward to the selection of bellwether

cases for trial in Spring 2015. That is less than a year away, and Defendants have yet to receive any discovery from Plaintiffs. And while the PSC is pressing forward aggressively with discovery against these Defendants, it is at the same time attempting to limit discovery of their clients to minimal information previously ordered by the Bankruptcy Court as part of the proof of claim process unless they self-select into the bellwether process. As explained below, the PSC's one-sided proposal leaves out key elements of a case management plan and will inevitably lead to further disputes over these preliminary matters that should be settled as soon as possible so that discovery and case development can get underway. Accordingly, the Saint Thomas Entities and Ascension Parties respectfully request that the Court consider their proposed CMO as to discovery and bellwether selections attached as Exhibit B.⁶ These Defendants are willing to meet and confer with all affected parties to attempt a compromise proposal for the deadlines, but, as evidenced by past negotiations, the PSC's position is that the discovery plan is unnecessary and their Bellwether Proposal is the only option. The Court needs to provide guidance as to overall structure of the discovery plan and bellwether scheduling order before further discussions can be fruitful.

II. The Bellwether Proposal Needs a Proper Framework, Balance, and Realistic Deadlines

The PSC is aggressively pushing this MDL to bellwether trials on an unrealistic schedule. It appears that the goal is to get dates in place so that it can pressure the Unaffiliated Defendants into procedures and processes designed to comply with those deadlines. The PSC has the process exactly backwards. The PSC presumably believes these overly ambitious deadlines for

⁶ These proposals were originally attached as Exhibits 2-3 to the Saint Thomas Entities' Response to Court's Directive in Further Support of Their Motion to Reconsider MDL Order No. 7 (Docket ##592-2 & 592-3), and Exhibit C to the Saint Thomas Entities' Notice of Status of Meet and Confer (Docket #863-3), although they have been combined and updated in Exhibit B.

designating bellwether plaintiffs are realistic because it has full access to all the records necessary to make these decisions—not only of the Plaintiffs it represents, but also those records currently residing in the NECC repository. Thus far, the Unaffiliated Defendants have been denied access to these critical documents.

The Saint Thomas Entities' proposed bellwether process follows largely on Judge Eldon Fallon's recommendations based on his experience in the Vioxx and Propulsid MDL proceedings. *See* Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2323-25 (June 2008). It provides, as Judge Fallon recommends, that the Plaintiffs provide completed Plaintiffs' Fact Sheets and executed authorizations for the release of medical and other records that will be necessary to evaluate the claims and affords them sufficient time to collect and review those records once the authorizations are provided and the records obtained. The proposed CMO also lines out an orderly process for defining selection protocols, selecting the initial pool of potential bellwether candidates ("Initial Pool"), and permitting further discovery of the Plaintiffs in the Initial Pool, culminating in the selection of four bellwether candidates for initial trials.

A. The Bellwether Process Must Be Carefully Designed

In appropriate circumstances, bellwether trials (also referred to as test cases) can be used to glean important information about the claims of the litigation as a whole. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 ("[T]o produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases."). Bellwether procedures have been used in an increasing number of mass tort MDLs.

See Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2324-25.⁷ As the Fifth Circuit has aptly summarized:

A bellwether trial designed to achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants has as a core element representativeness -- that is, the sample must be a randomly selected one of sufficient size so as to achieve statistical significance to the desired level of confidence in the result obtained. Such samples are selected by the application of the science of inferential statistics. The essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole.

In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019-20 (5th Cir. 1997). As a result, “[i]t is critical to a successful bellwether plan that an honest representative sampling of cases be achieved.” *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2010 WL 4024778, at *1 (S.D. Ill. Oct. 13, 2013); *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (“[T]est cases should produce a sufficient number of representative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis, and what range of values the cases may have if resolution is attempted on a group basis. The more representative the test cases, the more reliable the information about similar cases will be.”). As Judge Fallon indicated, “[i]f bellwether trials are to serve their twin goals as informative indicators of future trends and catalysts for an ultimate resolution, the transferee court and the attorneys must carefully construct the trial-selection process. . . . Any trial-selection process that strays from this path will likely resolve only a few independent cases and have a limited global impact.” Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2343. Based on his

⁷ The term bellwether “is derived from the ancient practice of bellring a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context.” *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997).

extensive experience in the Vioxx and Propulsid MDLs, Judge Fallon has set out important principles for selecting bellwether trials. He suggests that although there is no “one-size-fits-all” procedure, there are certain sequential steps that should be followed in crafting the protocols and processes. First, the MDL court must be in a position to catalogue the “Entire Universe of Cases,” meaning that it “conduct[s] a census of the entire litigation and identif[ies] all the major variables.” *Id.* at 2344. The next step is for the court and the attorneys for both sides to “creat[e] a pool of cases that accurately represents the different divisions within the MDL from which the bellwether cases will be selected.” *Id.* at 2346. Important to this step is deciding the size of the pool—“[i]f the pool is too small, then there is a risk that too few of the major variables will be properly represented.” *Id.* at 2347. To fill the pool, there are different methods—random selection, selection by the MDL court, and selection by the attorneys. *Id.* at 2348-49. And there are many variables within each strategy for filling the pool, all of which need to be geared to finding a truly representative, and therefore, credible, sampling. *Id.* at 2348-60. After the trial-selection pool has been determined, the parties conduct case-specific discovery. *Id.* at 2360. Then the third step is to select individual cases from the pool, which also can be done in a variety of ways depending on the facts and circumstances. *Id.* at 2360-65. The PSC has not adhered to this considered process.

B. The PSC’s Bellwether Proposal Provides No Assurance of Representative Cases

Although the PSC extols the virtues of bellwethers generally, it fails to explain how its proposal is designed to ferret out the truly representative cases, which must be the goal if the process is to achieve any success.

First, the PSC has not demonstrated that bellwether trials would be appropriate in these cases. *See, e.g., Auchard v. Tenn. Valley Auth.*, No. 3:09-CV-54, 2011 U.S. Dist. LEXIS 14771,

at *11-14 (E.D. Tenn. Feb. 2, 2011) (finding, after initial discovery, that bellwether cases were not appropriate because, based on the known information, the cases involving 450 plaintiffs were not numerous enough and there was insufficient commonality between the cases). This MDL is very atypical in a number of respects that bear on whether bellwether trials will produce meaningful results. Unlike most MDLs, the Affiliated Defendants who would be included in all of the MDL cases are either in bankruptcy or various stages of settlement with the PSC, likely leaving only national and local defendants to participate in the bellwether trials. The combination of the NECC bankruptcy and MDL proceedings makes this case quite unusual. The global settlement with the primary MDL defendants (NECC and its affiliates), if fully consummated, will necessarily impact how the claims against the remaining defendants will be tried. Assuming the manufacturer of the methylprednisolone acetate (“MPA”) at issue is removed from the MDL through release and/or discharge, the remaining defendants break down into a few “national defendants” (such as Unifirst, ARL BioPharma, and Liberty) and a large number of local health care providers that are subject to very divergent regulatory and legal regimes. Clearly, a verdict in a Virginia case against different, unrelated health care providers would provide no meaningful information for a trial involving Tennessee plaintiffs, Tennessee claims, and Tennessee health care providers. Thus, although the Saint Thomas Entities agree that bellwether trials can be very useful in an appropriate case, it should not be assumed here, as the PSC has done, that any individual case in this MDL will truly be representative of any other. Indeed, as the Court has previously noted:

My assumption from day one has been that when cases are ready for trial, they get spun out to the individual home districts where they first arose. Again, this seems to me putting aside the so-called national defendants that if what the case is against a pain clinic and a doctor, that probably those cases ought to be spun out for trial to where they originated.

I have not done any sophisticated thinking on that topic, and it obviously depends on what the cases look like and so on, but that's going to affect what cases are selected as bellwethers. All this by way of saying, this is not a typical case where, you know, you have pharmaceutical product X, and the question is did it cause injury Y, and was appropriate testing done and so forth.

I think that's not going to be the central issue in these cases, so it's not clear to me what this is going to look like, where these cases are going to be tried, and what the stage in the process we need to begin talking about that, but certainly it was too soon to be thinking about it a month ago, at least when we were issuing orders, and it's one more thing. I think we ought to formulate a step at a time. It depends very much what these cases look like, who the defendants are and what happens from there.

See Tr., Ex. A at 46. Second, assuming that test trials would be proper and useful here, it is premature to set deadlines when the universe of potential bellwether plaintiffs is far from known at this time. Many new cases are in the process of being filed in or transferred to this Court. Many of the Tennessee-law claims against the Saint Thomas Entities and Ascension Parties were subject to a one-year statute of limitations and so were brought into the MDL in September and October 2013, approximately one year after the recall of NECC's compounded products. These Defendants expect that a number of other health care providers located in states with two-year statutes of limitations will be brought into the MDL by October of this year. And the Centers for Disease Control and Prevention list and the PSC's Master Complaint both indicate that there are likely to be many more patients in these states with longer statutes of limitations who will likely file complaints in the coming months. Without any understanding of what the universe of potential bellwether plaintiffs and defendants will be, it is premature to set deadlines for making binding choices.

C. The Individual Plaintiffs' "Basic, Important Information" Is Needed to Guide the Bellwether Process

Indeed, the bellwether discussion should be deferred until the discovery process has been more thoroughly defined. *See, e.g., In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, No.

1:00-1898, MDL 1358(SAS), M21-88, 2007 WL 1791258, at *3 (S.D.N.Y. June 15, 2007) (approving plan developed after investigation and discovery revealed particular variables in litigation census). Here, the PSC wants the process completed in a matter of a few months, at a time when a large number of cases have yet to be filed or transferred to this MDL, and without affording sufficient time for the defendants to obtain Plaintiffs' medical and other records and information that is critical to the process. As Judge Fallon explains it:

The discretionary limitation that bellwether trial candidates be trial-ready should be imposed as a means to streamline the trial-selection process. . . . [I]n this context, trial-ready means that the attorneys have adequate proof of the important, basic information, [which includes] access to the plaintiffs' medical files The importance of being trial-ready in this sense, other than the accelerated manner in which the case can be prepared, is that it prevents the unfortunate situation where a case is proposed and accepted to fill the pool, but the attorneys later discover that the existence of one of these preliminary matters is uncertain or even challenged.

The parties will usually be required to provide all of this information early on in the litigation pursuant to a global pretrial discovery order. *See, e.g., In re Vioxx Prods. Liab. Litig.*, MDL No. 1657 (E.D. La. June 29, 2006) (pretrial order no. 18C) (governing the provision of Plaintiff Profile Forms, Merck Profile Forms, and medical authorizations); *In re Propulsid Prods. Liab. Litig.*, MDL No. 1355 (E.D. La. Jan. 31, 2001) (pretrial order no. 9) (governing the provision of Plaintiff Profile Forms and medical authorizations). Notwithstanding such a requirement, the parties may occasionally fail to provide this information. ***Cases in which this basic level of disclosure is not complete should not be considered for bellwether trials, and may even be subject to dismissal if the parties fail to comply after additional prompting.*** *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1232-34 (9th Cir. 2006); *Acuna v. Brown & Root Inc.*, 200 F.3d 335, 340-41 (5th Cir. 2000).

Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2352 & n.99 (emphasis added).

At a minimum, the Defendants should have access to the Plaintiffs' Fact Sheets and medical and other records. These items of discovery are part of the "basic, important information" that Judge Fallon has identified as necessary to the bellwether process. And that process is likely to reveal important litigation variables that should be considered in defining the bellwether process. Right now, there is virtually no data from which to determine the selection

of bellwether cases or if a bellwether process is even appropriate. As noted above, the PSC has thus far not provided *any* Fact Sheets or medical records for the individual Plaintiffs—records that are critical to assessing suitability and making decisions as to whether there are sufficiently representative plaintiffs. *See Morgan v. Ford Motor Co.*, No. 06-1080 (JAP) (Consolidated), 2007 U.S. Dist. LEXIS 36515, at *41-42 (D.N.J. May 17, 2007) (providing for Rule 26 conference and disclosures before parties’ selection of bellwether cases); *cf. Abrams v. Ciba Specialty Chems. Corp.*, No. 08-00068-WS-B, 2008 U.S. Dist. LEXIS 86487, at *16-19 (S.D. Ala. Oct. 23, 2008) (demonstrating the importance of having data and discovery to determine bellwether plaintiffs). Therefore, the PSC’s suggestion that bellwether plaintiffs can be chosen within 120 days of the Court’s order on Fact Sheets, Docket #837-1 at I.F, is impossible, as the deadline has already run. The other dates in the PSC’s proposed bellwether schedule have likewise either passed or are currently unworkable. *See* part II.D, below. The fact that discovery is in its infancy is yet another reason to continue to defer the bellwether selection process.

D. The Benchmarks Are Impossible

The intervals of events, even if shifted to account for the passage of time, are unworkable. For example, the PSC proposes that Plaintiffs and Defendants select four cases as candidates for the Initial Trial Pool within 120 days of the approval of the Fact Sheet by this Court—a date which has already passed. The PSC at the same time proposes that Plaintiffs be allowed 60 days to complete and execute the Fact Sheets and authorizations—and a 45-day window to identify and cure any material defects. What the PSC is essentially recommending is that Defendants will receive executed Fact Sheets and authorizations and—assuming they are all complete and contain no defects to cure—have less than two months to obtain, review, analyze, and synthesize all of the information and records for more than 100 plaintiffs to be in a position to pick the first bellwether cases. Considering that it typically takes 60 to 90 days to obtain

medical records after a valid authorization is presented to the provider, and the finalized Fact Sheets and authorizations will not be available to the Defendants under the PSC's proposal for at least another 45 days, this deadline is impossible.

The PSC also attempts to require Defendants to notify the PSC of any claimed deficiencies in the Fact Sheets within 15 days of receipt. Considering the number of Fact Sheets that are likely to come in at one time, this time limit is unreasonable.

The "Common Discovery Deadlines" are also far too ambitious considering all that must be accomplished during this phase. The PSC already has access to all of the documents both from its own clients, and from NECC in the document repositories, and so has a significant advantage in terms of the timing of this discovery. And at this point it is unclear precisely when these Defendants will have access to the same materials. Once they do, they will need time to review the 40,000 documents—and documents discovered from other parties in this case—to factor into the common discovery phase of this litigation. For analogous reasons, the time frames for expert discovery are unrealistic, especially when considering that, to the Saint Thomas Entities' knowledge, not a single expert has been designated in this litigation.

E. If Considered at all, the PSC's Bellwether Procedure Needs Revision

The PSC's proposed bellwether structure is fatally flawed. The Fallon article demonstrates the complexity and importance of that process, which should not be rushed. *See, e.g., Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 2007 WL 1791258, at *3 (approving plan developed after investigation and discovery revealed particular variables in litigation census). Further, much more work is needed to identify the critical "litigation variables." The PSC suggests that the only relevant "litigation variables" are "exposure to NECC-manufactured methylprednisolone acetate and diagnosis of resulting infection." Bellwether Motion at 14. But those factors are (or should be) common—not variable—factors for all Plaintiffs; presumably

none of the Plaintiffs would have filed a lawsuit without those minimum allegations. In *Vioxx* for example, the “major variables ultimately decided on . . . were (1) the type of injury (heart attack, stroke, or other), (2) period of ingestion (short-term versus long-term), (3) age group (older or younger than sixty-five), (4) prior health history (previous cardiovascular injuries or not), and (5) date of injury (before or after a certain label change).” Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2345. Although, in this case, discovery will likely be necessary to reveal the full panoply of variables, factors relating to acuity and co-morbid conditions will be significant litigation variables, as there are many individuals who were exposed to the contaminated NECC products who did not develop disease.

The PSC also proposes an arbitrarily small pool of potential candidates in the “Initial Trial Pool Cases”—only eight from the hundreds of MDL Plaintiffs selected by each side—which will guarantee a most unrepresentative sample for selection of the bellwether trials. This is far too small a bellwether pool to provide representative cases for test trials. *See id.* at 2346-47 (pool must be large enough to account for the major litigation variables). Considering that the litigation variables have yet to be identified, it is premature to estimate a number for the pool.

Also concerning is the fact that while the PSC promotes Judge Fallon’s bellwether orders in *Vioxx* and *Propulsid*, it then suggests an entirely different process that will not achieve similar results. Under the PSC’s proposal, the eight cases will be chosen by the litigants for full discovery and then the Court will choose the first two of those eight for initial trials, but all eight will be the effective bellwether pool. Judge Fallon did not provide the two sides with the unfettered right to choose. As the PSC notes, he permitted each side to have strikes so that the outliers could be eliminated. But under the PSC’s proposal, there is no vetting process to eliminate outlier cases. Further, there is no information as to whether the parties will agree to a

Lexecon waiver. In *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 34 (1998), the U.S. Supreme Court held that the MDL transfer statute, 28 U.S.C. § 1407, does not permit the transferee court to try cases that were not originated under its jurisdiction absent agreement by the parties. In *In re Yasmin*, the court found “such a waiver to be critical to the success of th[e bellwether] endeavor.” 2010 WL 4024778, at *1. Without that information, it is impossible to know whether any of the cases will be tried by this Court in Boston or elsewhere throughout the country. In other words, the Court may have to transfer a large percentage of these cases back to their transferor courts for trial (or travel around the country trying the cases in their native venues). It makes no sense to defer this decision until after the bellwethers are actually chosen, as it is important to the bellwether process to know where and by whom the test cases will be tried.

Finally, there is no contingency plan if a case is dismissed or settled on the eve of trial. There should be a procedure or protocol for substituting a new bellwether case—for example, if the Plaintiff is permitted to unilaterally dismiss the case after full case development, Defendants should be able to choose its replacement.

These objections should by no means be viewed as an exhaustive list of problems with the PSC’s Second Bellwether Proposal. Instead, they should illustrate the reasons why the Court should proceed with caution in considering the PSC’s precipitous proposal.

CONCLUSION AND PRAYER

Therefore, the Saint Thomas Entities and Ascension Parties respectfully request that the Court enter orders: (a) granting the Saint Thomas Entities’ Discovery Motion; (b) staying all further discovery pending entry of a comprehensive discovery plan; (c) superseding all prior case management orders to the extent inconsistent with the Court’s consideration of a discovery plan and amended case management order; (d) ordering the parties to meet and confer regarding a

proposed discovery plan and bellwether proposal—with direction from the Court as to the elements of both, and return to the Court with a joint proposal, if possible, or alternatives; (e) denying the PSC’s Bellwether Motion; (f) alternatively, entering the proposal for an amended CMO attached as Exhibit B; and (g) granting such other and further relief to which these parties are entitled.

Dated: July 8, 2014

By its attorneys,

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CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 8th day of July, 2014.

/s/ Sarah P. Kelly
SARAH P. KELLY